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Legislative Notice

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S. 343 — The Comprehensive Regulatory Reform Act of 1995

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Reported from the Senate Committee on the Judiciary on May 26, 1995, with amendments in the nature of a substitute. S. Rept. 104-90. Additional and supplemental views filed. A Dole/Johnston substitute is expected to be offered during floor consideration.

NOTEWORTHY

- The Republican Leader announced his intention to take up S. 343 on Tuesday, June 27.

- This Notice addresses a bipartisan discussion draft substitute for S. 343 that is expected to be offered by Senators Dole, Johnston, Hatch, Heflin, Roth and Murkowski. The substitute draft, which can be found in the June 21 *Congressional Record*, beginning on page S-8795, is based on S. 343 as reported from the Committee on the Judiciary, but with modifications suggested by Senators Johnston and Heflin, the Administration, and the American Bar Association, and with some provisions and concepts from S. 291 [unaninously reported from the Committee on Governmental Affairs on May 25, 1995 (Rept. 104-88)], and S. 333 [reported on a party-line vote by the Committee on Energy and Natural Resources on May 25, 1995 (S. Rept. 104-87)].

- The Dole/Johnston substitute recodifies and modifies the Administrative Procedures Act [P.L. 89-554], amplifying improvements to the APA that passed the Senate in 1982 by a vote of 94-0 (S. 1080).

- In addition, the substitute requires that agencies, where not prohibited by the underlying statute, select regulatory options in which benefits justify the costs. This requirement is judicially reviewable. It also standardizes agency science regarding risks of hazards; extends judicial review to and expands the Regulatory Flexibility Act; reforms the Delaney Clause; and includes, with minor changes, the congressional oversight bill, S. 219, which passed the Senate on March 29, 1995, by a vote of 100-0.

HIGHLIGHTS

The Dole/Johnston discussion draft substitute, like S. 343, is intended to reduce unnecessary federal regulation. Federal regulatory costs have been estimated variously between $450 billion to $850 billion annually, imposing as much as $6,000 in costs per household per year. But the significant issue is not so much the magnitude of the cost of regulations, but whether Americans are getting their money's worth of protection.

- The Dole/Johnston substitute requires agencies to conduct a cost-benefit analysis, and a risk assessment where appropriate, and directs the agencies to select, where not prohibited by the underlying statute, rules in which the benefits justify the costs. These requirements supplement, but do not override, statutory criteria, thus this cost-benefit requirement is not a "supermandate."

  - Federal agencies are directed to conduct cost-benefit analyses during the promulgation of all major rules (rules having a gross effect on the economy of $50 million or more in any one year). Unless prohibited by the underlying statute, agencies are directed to select the regulatory options in which the benefits of the rule justify the rule's costs.

  - Risk assessments are to be standardized and should reflect the best available science, with public participation and peer review.

- The substitute will subject the agencies' use of the new cost-benefit rules to judicial review under an "arbitrary and capricious" or "abuse of discretion" review standard. This provision is intended to force the agencies to do what Congress requires under this legislation, but not result in reversal of rules for an agency's failure to follow procedures that do not materially affect the outcome of the rule.

- The core of S. 343, and of the substitute, is an updated version of a 1982 bill to reform the Administrative Procedures Act, S. 1080, the Regulatory Reform Act, which passed the Senate 94-0, but died in the House.

- The substitute also subjects virtually all final rules to a 60-day expedited congressional review procedure. This provision is similar to S. 219, which passed the Senate 100-0 on March 29, 1995. (S. 219 provided a 45-day review period, and defined major rules as having a $100 million impact, instead of $50 million, as in this legislation.)

- The substitute reforms the Delaney Clause of the Federal Food, Drug, and Cosmetic Act, which currently requires that processed foods may not be sold if they contain even trace amounts of chemicals that have been demonstrated to cause cancer in humans or animals.

- The measure provides for expansion and court enforcement of the Regulatory Flexibility Act of 1980, an act largely ignored until now, that requires agencies to minimize the impact on small business when promulgating rules.

BACKGROUND

No one disputes the fact that federal regulations have increased the health and safety of Americans and the environment. However, in the last 30 years, the pace of regulation has been increasing while their marginal benefits have generally declined. Moreover, modern science now allows regulators to measure parts per billion or even parts per trillion of a chemical in water or air. Agencies charged with protecting the public simply do not adequately consider the dramatic increases in costs of trying to remove the last molecule of a chemical. Finally, the Clinton Administration, until this spring, has been accelerating the promulgation of rules, reaching a total of 64,914 actual pages of regulations and notices published in the *Federal Register* during 1994, second only to the number of pages published during President Carter's last two years in office. In contrast, President Reagan with help from a Republican Senate, reduced the actual pages down to 44,812 in 1986.

While under the Reagan and Bush Administrations, agency regulatory oversight was a priority and overseen by the Office of Management and Budget, under Clinton's Executive Order 12866, issued on October 4, 1993, OMB oversight has been significantly downgraded. The result has been an out-of-control activist federal regulatory juggernaut, unveiled in the Administration's first Regulatory Plan released with the Unified Regulatory Agenda in November 1994. For example, the Clinton Administration's Office of Information and Regulatory Analysis in OMB did not reject or return any of the EPA's 45 significant ($100 million in cost per year or more) regulatory action proposals during the April to September 1994 timeframe. Accordingly, economist Thomas Hopkins' famous projections of regulatory costs, published in 1991 and revised in 1992, significantly understate the additional regulatory costs being imposed on the American economy since 1993. Even so, Hopkins' 1992 projections estimated that the direct compliance burden in 1995 would total over $600 billion (almost $6,000 per household), with environmental compliance comprising $150 billion of that total.

The fact that so much money and resources are being spent to comply with federal regulations has raised the legitimate concern over whether that money is being spent wisely. For example, Americans have spent almost $2 trillion on direct compliance with environmental regulations since 1970, and they have every right to demand that their $150 billion per year in current environmental compliance expenses is used wisely, especially compared to efforts to mitigate other health risks. Many people have concluded that if priorities were better set, risk regulation could be improved without increasing the overall cost of regulation. A March 1995 publication of the Harvard School of Public Health cites a study

conducted of 200 federal programs designed to reduce risk, noting that many highly cost-effective programs were not fully implemented, while other highly cost-ineffective programs were widely implemented. As a result, it concludes that a reallocation of resources to more cost-effective programs could save an additional 60,000 lives per year at no increased cost to taxpayers or the private sector. Alternatively, the country could save the same number of lives we are currently saving, but do so at a $31 billion annual savings to taxpayers and the private sector.

The Congress has already completed action on the Unfunded Mandates Act (P.L. 104-4, which, among other things, requires agencies to conduct cost-benefit studies before proposing new regulations), and the Paperwork Reduction Act (P.L. 104-13, which sets a target of 10 percent reduction in annual paperwork imposed by agencies on the private sector and state and local governments). In addition, the House has passed a moratorium on major regulatory actions pending passage of a comprehensive regulatory reform bill, and the Senate has passed a 45-day congressional review (S. 219) to provide a procedure for considering a resolution of disapproval for all final agency rules. The resolution of disapproval, once passed by both Houses and presented to the president, would declare a final rule null and void. S. 219 is in conference with the House regulatory moratorium bill (originally H.R. 450).

However, comprehensive changes directed toward getting the attention of agencies to conduct unbiased risk assessments and cost-benefit analysis — with judicial review to ensure compliance — is the most critical legislation under consideration this Congress for the reduction of regulatory burdens on small business and the economy generally. The House passed H.R. 9 on March 3, 1995, which contains H.R. 1022 (risk assessment) and H.R. 926 (cost-benefit analysis).

BILL PROVISIONS

Senators Dole, Johnston, Hatch, Heflin, Roth and Murkowski are expected to offer a discussion draft substitute to S. 343. The substitute is based on S. 343 as reported from the Committee on the Judiciary, but with modifications suggested by Senators Johnston, Heflin, the Administration, and the American Bar Association, along with some provisions and concepts from S. 291, reported unanimously from the Committee on Governmental Affairs on May 25, 1995 (Rept. 104-88), and S. 333, reported on a party-line vote by the Committee on Energy and Natural Resources on May 25, 1995 (Rept. 104-87).

A summary of the Dole/Johnston discussion draft substitute is presented on the following pages.

The substitute recodifies the Administrative Procedures Act (5 U.S.C. 551, et. seq.) and makes the following changes (APA section numbers are in parentheses):

RULEMAKING (Sec. 553) — This section rewrites section 553 of the Administrative Procedures Act, which governs informal (notice and comment) rulemaking.

DEFINITION OF MAJOR RULE (Sec. 621) — The substitute generally covers only "major rules," defined as a rule or set of closely related rules that has a gross annual effect on the economy of $50 million or more in reasonably quantifiable increased costs in any one year. "Major rules" do not include rules of particular applicability (such as rate approvals), rules involving the Internal Revenue laws, rules relating to management or personnel practices of an agency, annual rules, rules that provide relief from a statutory provision, all rules issued by financial agencies, and rules relating to national security or foreign affairs functions of the United States. An agency's determination that a rule is not a "major rule" is judicially reviewable.

RULEMAKING COST-BENEFIT ANALYSIS (Sec. 622) — This section sets standards for cost-benefit analyses for major rules, and requires that agencies publish a summary of the analysis in the *Federal Register* in the Notice of Proposed Rulemaking and again in the Final Rule. A major rule may be made effective without a cost-benefit analysis if the agency "for good cause" finds an emergency or health or safety threat that is likely to result in significant harm to the public. However, the agency must complete a cost-benefit analysis on such a rule within 180 days after the rule is finalized, and revise the rule, as necessary. In considering costs and benefits in their analyses, the agencies are to calculate both costs and benefits using qualitative as well as quantitative data to describe the "reasonably identifiable incremental favorable (or adverse) effects."

AGENCY REVIEW AND PETITION (Sec. 623) — The substitute requires each agency to promulgate a list of existing regulations that the agency feels are appropriate for review, along with a schedule for systematic agency review of those regulations over a ten-year period. The agency must apply to each of these listed rules the cost-benefit requirements imposed by this legislation and decide whether to extend, modify or rescind the rules. All rules on the schedule that are not reviewed by the deadlines provided in the agency's schedule (with one two-year extension possible), will automatically expire. [Note: the agency costs incurred by this review are to be separately identified in the annual budget and the appropriations committees may alter the schedules when appropriating funds for this review.]

In addition, petition mechanisms are provided for any interested party to add major rules to a schedule and to petition the agency for earlier consideration of a particular rule already on a schedule. The agencies must grant the petition to add a major rule to a schedule if the agency finds there is a "reasonable likelihood" that the future impacts of the rule would not meet the cost-benefit tests imposed by this legislation. Judicial review is provided for all final agency actions in this review and petition process, including the promulgation of the schedule, decisions on whether to extend, modify or rescind the rules on the schedule, and denials of petitions.

DECISIONAL CRITERIA (Sec. 624) — Federal agencies are directed to conduct cost-benefit analyses during the promulgation of all major rules (rules having a gross effect on the economy of $50 million or more in any one year). Unless prohibited by the underlying statute, agencies are directed to select the regulatory options in which the benefits of the rule justify the rule's costs. This directive is supplemental to the criteria contained in the underlying statute, and does not override statutory criteria. Thus, the directive to select an option in which the benefits justify the costs is not a "supermandate." For example, this directive would not contradict an underlying statute that specifies that the agency pick regulatory options that maximize protection of human health, notwithstanding the costs; but it would require the agency to select among the least costly options, including use of market mechanisms where practicable, that meet the "maximize protection of human health" criterion.

- Unless prohibited by the underlying statute, agencies must select among options in which the benefits justify the costs. Among those options, the agency must select the option that employs, to the extent practicable, flexible (market-mechanisms) alternatives. Finally, the option selected by the agency must also meet one of the following two conditions: either

  1) it is the least-cost alternative of the allowable options that achieve the objectives of the statute;

  or

  2) it may be a more costly alternative if the agency determines that nonquantifiable benefits to health, safety, or the environment or scientific, technical, or economic uncertainties make the more costly alternative "appropriate and in the public interest." However, the agency must adopt the least-cost alternative allowed by the statute that takes into account these uncertainties or benefits.

- If the underlying statute does **not** permit the agency to select an option in which the benefits justify the costs, the agency still must select an option allowed by the statute that employs, to the extent practicable, flexible (market-mechanisms) alternatives. In addition, the option selected by the agency must also meet one of the two conditions described immediately above.

JUDICIAL REVIEW (Sec. 625) — This section directs the courts to review, under the existing APA "arbitrary and capricious" or "abuse of discretion" review standard, an agency's determination of whether a rule is a "major rule" subject to cost-benefit and risk assessment requirements, and also whether the benefits justify the costs. There is, however, no "interlocutory" (before a final rule is issued) judicial review in a rulemaking proceeding. Judicial review is available only at the final rule stage. The "prejudicial error" standard, recodified in the new section 706, discussed below, recodifies the APA principle that agency failure to comply with procedures established by this legislation is not a separate ground to overturn the rule unless that failure was "material" and would have changed the outcome of the rule.

DEADLINES FOR RULEMAKING (Sec. 626) — Current deadlines (including court-ordered deadlines) for agency rules are suspended until such time as the cost-benefit analyses required by this substitute are completed.

REQUIREMENTS FOR MAJOR ENVIRONMENTAL MANAGEMENT ACTIVITIES (Sec. 628) — The relevant agencies (mostly the EPA) must conduct a risk assessment (Sec. 631) for all major environmental management activities unless construction at that site has already commenced, and 1) it is more cost-effective to complete construction than apply the risk assessment requirements of this substitute; or 2) delays caused by the requirement to do a risk assessment will result in an "actual and immediate risk to human health or welfare." A "Major Environmental Management Activity" is any environmental cleanup action costing at least $10 million (including damages), for which construction has not commenced on the date of enactment of this legislation, for: corrective actions required under the Solid Waste Disposal Act ("RCRA"); Superfund; correction of radioactive (or mixed radioactive and hazardous wastes); or actions pursuant to federal guidelines for the conduct of such cleanup activities.

SUBCHAPTER III — RISK ASSESSMENTS (Secs. 631-637) — The substitute establishes standardized "risk assessments" conducted by federal agencies for all proposed and final "major rules," a primary purpose of which is to protect human health or safety, or the environment, or a consequence of which is a "substantial substitution risk." Agencies must comply with this subchapter for "major agency guidances" and "major environmental management activities." However, risk assessments do not have to be performed pursuant to this subchapter for: emergencies; rules or actions introducing a product into commerce; actions under the Federal Insecticide, Fungicide, and Rodenticide Act; actions under the Toxic Substances Control Act; and human health, safety, or environmental inspections or permits (except RCRA hazardous waste disposal permits would be required to comply with this Act). This subchapter requires the use of the best reasonably available scientific information, encourages the use of postulates, and forbids agencies from inappropriately compounding multiple postulates. The subchapter also establishes "Principles for Risk Characterization" (Sec. 634) to standardize risk characterizations and make them more clear, including a requirement that the risk being analyzed must be compared to other risks that are familiar to, and routinely encountered by the general public. This subchapter also requires each agency to develop a systematic program for independent and external peer reviews of each risk assessment required under this subchapter, which shall be made available to the public. Finally, this subchapter requires agencies to prioritize risks that are the most serious and can be addressed in a cost-effective manner, with a goal of achieving the greatest overall net reduction in risks with the public and private sector resources expended.

SUBCHAPTER IV — EXECUTIVE OVERSIGHT (Secs. 641-645) — This subchapter contains the following provisions:

- OMB is required to issue guidelines to implement the cost-benefit and risk assessment requirements of this legislation;

- agencies are required to list all ongoing or planned risk assessments in the semi-annual Unified Agenda of Federal Regulations;

- the Regulatory Flexibility Act of 1980 is amended to permit an affected small entity to petition, within one year of the effective date of the final rule, for judicial review of the agency's compliance or noncomplaince with the Regulatory Flexibility Act;

- the way EPA and HHS implement the Delaney Clause of the Federal Food, Drug, and Cosmetic Act is reformed, which currently requires that processed foods may not be sold if they contain even trace amounts of chemicals that have been demonstrated to cause cancer to humans or animals. The substitute provides that federal agencies may not refuse to approve a product on the basis of safety, where the "substance or product presents a negligible or insignificant foreseeable risk to human health resulting from its intended use"; and

- the Administrator of the EPA is required to review the November 30, 1994, final rule that added several hundred new chemicals and chemical families to the Toxic Release Inventory. The Administrator is required to remove any substance from the list if its removal is justified by the Administrator's determination whether removal of the substance from the list presents a foreseeable significant risk to human health or the environment.

SCOPE OF REVIEW (Sec. 706) — This section amends section 706 of the Administrative Procedures Act, which establishes the scope of judicial review of final agency actions. The existing APA section is amended to clarify that the courts shall review agency findings of fact using the traditional "unsupported by substantial evidence" standard, which is the appropriate standard of judicial review for agency fact-finding determinations.

CONSENT DECREES (Sec. 707) — This new APA section declares unenforceable any agency consent decree agreed to in settlement of a lawsuit if that consent decree limits the discretion available to an agency under a statute.

AFFIRMATIVE DEFENSE (Sec. 708) — This new APA section creates an "affirmative defense" to defendants in an agency enforcement action where the defendant must comply with a regulation that is contradictory or duplicative of another regulation.

CONGRESSIONAL REVIEW OF AGENCY RULEMAKING (Sec. 801) — This section is almost identical to S. 219, which passed the Senate 100-0. This provides that Congress may, by a joint resolution of disapproval presented to the president, overturn any agency final rule, with exceptions for rules of particular applicability, rules regarding monetary policy, and internal agency rules. If Congress does not act within the 60-day (instead of the 45-day period contained in S. 219, as passed) period, final major rules become effective (non-major final rules are not delayed by this section). Major rules (rules costing at least $50 million instead of the $100 million threshold contained in S. 219, as passed) may not become effective during the review period.

COST

Although there is no Congressional Budget Office estimate for the substitute, in a letter to the Committee on the Judiciary dated May 18, 1995, the CBO stated that enactment of S. 343 as reported by the committee could affect direct spending by increasing the total costs to agencies of conducting cost-benefit analyses for new rules, and for reviewing existing rules to meet the bill's sunset provisions. The CBO noted that agencies already perform cost-benefit studies for all regulations over $100 million per year, and estimated the additional cost of conducting cost-benefit analyses for regulations costing between $50 million and $100 million per year would add at least $140 million to $160 million annually to the cost of issuing regulations. In addition, the CBO estimated that costs to review existing rules pursuant to the five-year sunset for new rules and seven-year sunset for existing rules would "probably" range from $20 million to $40 million annually.

Estimated Cost to State and Local Governments

CBO also estimated that it had no basis for "predicting the direction, magnitude, or timing" of the impacts of S. 343 on state and local governments. [Effective January 1, 1996, CBO will be required to prepare estimates of the costs and benefits of federal mandates on state, local and tribal governments and on the private sector pursuant to the Unfunded Mandates Act of 1995 (P.L. 104-4).]

Evaluation of Regulatory Impact

Section 11(b) of rule XXVI of the Standing Rules of the Senate requires publication in the report of the committee's estimate of the regulatory impact of the bill as reported. The committee simply stated that it had concluded that "S. 343 will have significant regulatory impact." In addition, however, the committee report provides thorough elaboration of the nature of the regulatory impacts in the discussion of the various sections of the bill.

OTHER VIEWS

Senators Biden, Kennedy, Leahy, Simon, Kohl, and Feingold

The Senators state that the "primary function of government is to protect the public's health and safety," and that S. 343 as reported would "displace Congress as the arbiter of the ideal that the safety of the people is our highest priority and elevate instead the narrow, self-interested concerns of private parties." They point to the track record of federal regulations in cleaning up rivers and protecting workers. The Senators embrace the need for regulations to prevent a repeat of thalidomide use, cryptosporidium in the water supply, Three Mile

Island, Love Canal, or E. coli bacteria in hamburgers. The Senators assert that instead of a sweeping change in regulatory principles, the Congress should consider the appropriateness of applying the principles in the bill to each separate authorizing statute, which were enacted to address a specific set of problems. A number of the specific concerns raised in their additional views are directed at provisions that have been modified in the substitute, or dropped entirely, such as the "supermandate" (which would have required agencies to select an option where the benefits justify the costs even if the underlying statute directs the agency to select a different option). They state that one of the most serious flaws in the bill as it was reported was the proposal to repeal the Delaney Clause, adding that current law should not be changed unless it is replaced with "a scientific standard that sufficiently protects the public from cancer-causing chemicals."

Senator Leahy

The Senator is concerned that this is a "regulatory policy" bill that makes better regulations nearly impossible. He asserts that the bill does not protect the public from government, but is instead, "a profoundly anti-democratic, elitist bill." He, as one of the sponsors of the 1982 Regulatory Reform Act, takes issue with the assertion made by bill proponents that S. 343 is "just an updated form of S. 1080." He states that the bill turns cost-benefit analysis from a useful decision-making tool into a rigid rule because it would be a "decisional criterion." The Senator raises 120 possible grounds for appealing an agency decision upon enactment of S. 343. Finally, the Senator challenges the assertion that regulatory costs are increasing, by noting that since GDP is increasing faster than inflation, Thomas Hopkins' 1991 projections of outyear regulatory burdens — expressed as a percentage of GDP — are holding flat since 1991 and actually are beginning to decrease.

Senator Kohl

The Senator emphasizes the need for bipartisan regulatory reform that includes cost-benefit analysis and risk assessment. However, the Senator is concerned that the provisions of S. 343 undermine its own cost-benefit goals, citing as an example the petition processes which would empower a single party to drown a popular rule in agency paperwork.

Senator Feingold

The Senator agrees that there is a need to introduce a mix of common sense and sound science to the regulatory process, but believes that S. 343 does not strike the correct balance between adequately safeguarding health and safety and granting greater relief to those being regulated.

ADMINISTRATION POSITION

The Administration has been vocally opposed to any regulatory reform legislation that would allow the courts to enforce guidelines on the agencies. A specific message has not been received expressing an opinion on the bipartisan discussion draft substitute.

POSSIBLE AMENDMENTS

When available, a list of possible amendments will be provided in an update to this Notice.

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